EFGCP Annual Conference 2017

Meeting the Ethical Standards under the Clinical Trials Regulation:

the Burning Questions (and Answers) for Researchers, Sponsors and Patients

21 & 22 February 2017

BluePoint Conference Centre
Brussels, Belgium

Organised by

EFGCP
where science and ethics meet

In partnership with:

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Conference Rationale

The Clinical Trial Regulation is now less than 2 years away and if we are to grasp this opportunity to improve research and regulation for patient benefit it is imperative we look together (public, patients, researchers and regulators) at both the procedural requirements of and ethical changes required.

As one of the most important, longstanding, European fora for debate around clinical research, bringing all interested parties together, the European Forum for Good Clinical Practice has taken an active role in the approaching the new CTR (*EFGCP Multi-Stakeholder Workshop & Discussion on How to Ensure Optimal Ethical Review within the New Clinical Trials Regulation?*13th April, MCE Conference Centre, Belgium). The 2017 Annual Conference will discuss procedural arrangements already underway and address the ethical challenges that the CTR present, providing opportunity for debate, access to expertise and examples of how these challenges can be met. Workshops with people who can support and help you to solve your problems will be organised.

Programme Committee

Hugh Davies	Health Research Authority (HRA), United Kingdom
Sini Eskola	European Federation of Pharmaceutical Industries and Associations, Belgium
Kim Champion	University College London (UCL), EFGCP, United Kingdom
Nicky Dodsworth	Premier Research, EFGCP, United Kingdom
Belen Granell Villen	Association of the British Pharmaceutical Industry (ABPI), United Kingdom
Kaisa Immonen	European Patients' Forum (EPF), Belgium
Eric Klasen	Medtronic, EFGCP, Switzerland
Ingrid Klingmann	Pharmaplex, EFGCP, Belgium
Marianne Maman	Novartis Pharma, Switzerland
Heather Sampson	University of Toronto, Office of Research Michael Garron Hospital, Canada
Mary Lynne Van Poelgeest	World Federation of Incontinent Patients, EFGCP, the Netherlands
Florian von Raison	Novartis Pharma, Switzerland
Frank Wells	EFGCP, United Kingdom

Faculty

Oliver Bisazza	Medtronic, Belgium
Kerstin Breithaupt-Grögler	kbr, Clinical Pharmacology Services, Germany
Xavier Carné	Hospital Clinic de Barcelona, Spain
Anna Chioti	Luxembourg Institute of Health (LIH), Luxembourg
Giulio Maria Corbelli	European AIDS Treatment Group (EATG), Italy
Bill Davidson	Health Research Authority (HRA), United Kingdom
Hugh Davies	Health Research Authority (HRA), United Kingdom
Nikos Dedes	Positive Voice & NEAT, Greece
Lode Dewulf	UCB, Doctors Of The World, Belgium
Nicky Dodsworth	Premier Research, EFGCP, United Kingdom
Elmar Doppelfeld	European Network of Research Ethics Committees (EUREC), Germany
Sini Eskola	European Federation of Pharmaceutical Industries and Associations, Belgium
Susan Forda	Lilly, EFPIA Scientific Regulatory and Manufacturing Policy Committee European, United Kingdom
Jozef Glasa	Slovak Medical University/Institute of Medical Ethics & Bioethics, EFGCP, Slovakia
Dianne Gove	Alzheimer Europe, Luxembourg

Marco Greco	European Patients' Forum, Italy
Andrea Heckenberg	Medical University of Vienna, Austria
Ingrid Klingmann	Pharmaplex, EFGCP, Belgium
Greg Koski	Alliance for Clinical Research Excellence and Safety (ACRES), Massachusetts General Hospital, Harvard Medical School, USA
Jane Lamprill	Paediatric Research Consultancy, United Kingdom
Sylvia Lobo	Pfizer, United Kingdom
Marianne Maman	Novartis Pharma, Switzerland
Anastassia Negrouk	European Organisation for Research & Treatment of Cancer (EORTC), Belgium
Martin O'Kane	Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom
Tom Quinn	Kingston and St George's Joint Faculty, United Kingdom
Joanna Robaczewska	EUPATI Fellow, Hasselt University, Belgium
Heather Sampson	University of Toronto, Office of Research Michael Garron Hospital, Canada
Thomas Schindler	BoehringerIngelheim, Germany
Ernst Singer	Medical University of Vienna, Austria
Paul Strickland	Strickland Quality Assurance, EFGCP, United Kingdom
Mary Lynne Van Poelgeest	World Federation of Incontinent Patients, EFGCP, the Netherlands
Beat Widler	Widler&Schieman, Alliance for Clinical Research Excellence and Safety (ACRES), Switzerland

Conference Language

The language of the Conference will be English.

Registration & Information

E-mail conferences@efgcp.eu or visit www.efgcp.eu

Conference Venue

BluePoint Conference & Business Centre Brussels
80 Bd. A. Reyers
BE-1030 Brussels
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Support the conference with corporate or institutional sponsoring

EFGCP has decided to open sponsoring opportunities - both corporate with companies and institutional with universities, NGOs and associations - to support this key discussion. Every organisation is invited to contribute to the success of this event while interacting directly with all major stakeholders involved in clinical research, sharing your opinions with peers and renowned experts, and being among the first to learn about the latest development on the topic! Ask for detailed information at info@efgcp.eu.

Programme

Tuesday, 21st February 2017

08:15 *Registration and Welcome Coffee*

09:00 Welcome
Ingrid Klingmann, Pharmaplex, EFGCP, Belgium

PLENARY SESSION 1
WHAT OPPORTUNITIES DOES THE CTR GIVE US TO IMPROVE RESEARCH AND HEALTH?

Chairpersons*: Sini Eskola, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium & Mary Lynne Van Poelgeest, World Federation of Incontinent Patients (WFIP), EFGCP, The Netherlands*

09:05 What is different about the CTR? What are its opportunities?
Anna Chioti, Luxembourg Institute of Health (LIH), Luxembourg

09:25 How can we use CTR to make research and healthcare better?
Marco Greco, European Patients' Forum, Italy

09:45 Current proposals for collaboration between Competent Authorities and RECs
Martin O'Kane, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom

10:05 Questions & Discussion

11:00 *Coffee Break*

PLENARY SESSION 2
NEW ETHICAL ISSUES RAISED IN THE CLINICAL TRIAL REGULATION

Chairpersons: *Oliver Bisazza, Medtronic, Belgium & Nikos Dedes, Positive Voice & NEAT, Greece*

11:30 Involving lay representation as required by the Regulation: what is their role and how should this be discharged in RECs
Giulio Maria Corbelli, European AIDS Treatment Group (EATG), Italy

11:50 What opportunity does the CTR offer for Research involving pregnant women?
Lode Dewulf, UCB, Doctors Of The World, Belgium

12:10 Emergency research: the continuing challenge and how can we develop a harmonized approach across Europe?
Tom Quinn, Kingston and St George's Joint Faculty, United Kingdom

12:30 Questions & Discussion

13:00 *Lunch*

BREAK-OUT SESSION - WORKSHOPS1-2-3

14:00 Workshop 1: How should RECs work across EU to harmonise review under the CTR?
Chair: ***Elmar Doppelfeld***, *European Network of Research Ethics Committees (EUREC), Germany*
Rapporteur: ***Hugh Davies***, *Health Research Authority (HRA), United Kingdom*

Workshop 2: Ethical Issues in Low-Intervention Clinical Trials
Chair: ***Andrea Heckenberg***, *Medical University of Vienna, Austria*
Rapporteur: ***Xavier Carné***, *Hospital Clinic de Barcelona, Spain*

Workshop 3: Ethical Aspects of Risk-Based Monitoring under the new CTR
Chair: ***Nicky Dodsworth***, *Premier Research, EFGCP, United Kingdom*
Rapporteur: ***Sylvia Lobo***, *Pfizer, United Kingdom*

15:30 *Coffee Break*

16:00 Feedback from Workshops 1-2-3
Chair: ***Jane Lamprill***, *Paediatric Research Consultancy, United Kingdom*

PLENARY SESSION 3
THE JOSEPH HOET LECTURE ON ETHICS IN CLINICAL RESEARCH

Chairperson: ***Ingrid Klingmann***, *Pharmaplex, EFGCP, Belgium*

16:30 Ethical Performance under the Clinical Trial Regulation
Ernst Singer, *Medical University of Vienna, Austria*

17:00 EFGCP Annual General Meeting (for EFGCP Members)

18:30 EFGCP Annual Conference Social Event

Wednesday, 22nd February 2017

08:30 *Welcome Coffee*

PLENARY SESSION 4
CONSIDERATIONS ON TRANSPARENCY, CONSENT AND THE CTR

Chairperson & moderator: ***Heather Sampson***, *University of Toronto, Office of Research Michael Garron Hospital, Canada*

09:00 Transparency: how it will affect research involving drugs and devices
Bill Davidson, *Health Research Authority (HRA), United Kingdom*

09:20 Questions & Discussion

09:30 Oxford Debate on: Clinical Trial Regulation will add little to help medicines research, promote patient rights or improve our health; it will be a barrier rather than a solution.

For the motion*: Greg Koski, Alliance for Clinical Research Excellence and Safety (ACRES), Massachusetts General Hospital, Harvard Medical School, USA*

Against the motion: *Hugh Davies, Health Research Authority (HRA), United Kingdom*

10:20 Summary

10:30 *Coffee Break*

BREAK-OUT SESSION - WORKSHOPS4-5-6

11:00 Workshop 4: What does CTR mean for the constitution and proper working of RECs?
Chair: *Jozef Glasa, Slovak Medical University/Institute of Medical Ethics & Bioethics, EFGCP, Slovakia*
Rapporteur: *Ingrid Klingmann, Pharmaplex, EFGCP, Belgium*

Workshop 5: Writing lay summaries for drugs and devices research
Chair: *Kerstin Breithaupt-Grögler, -kbr- Clinical Pharmacology Services, Germany*
Rapporteur: *Thomas Schindler, BoehringerIngelheim, Germany*

Workshop 6: CTR and the vulnerable: focus on people with Alzheimer's Disease
Chair: *Dianne Gove, Alzheimer Europe, Luxembourg*
Rapporteur: *Marianne Maman, Novartis Pharma, Switzerland*

12:30 *Lunch*

13:30 Feedback from Workshops 4-5-6
Chair: Paul Strickland, Strickland Quality Assurance, EFGCP, United Kingdom

PLENARY SESSION 5
DESIGNING THE FUTURE OF THE CLINICAL TRIAL

Chairpersons: *Beat Widler, Widler&Schieman, Alliance for Clinical Research Excellence and Safety (ACRES), Switzerland & Joanna Robaczewska, EUPATI Fellow, Hasselt University, Belgium*

14:00 CTR and radical new concepts in treatments: is the CTR help or hindrance? Changing models of research and the CTR: how do we "futureproof" regulations and provide flexibility so we don't hinder innovative treatment drug developments
Anastassia Negrouk, European Organisation for Research & Treatment of Cancer (EORTC), Belgium

14.20 CTR and adaptive study design: flexibility should be the key
Susan Forda, Lilly, EFPIA Scientific Regulatory and Manufacturing Policy Committee European, United Kingdom

14:40 Europe, the CTR and research across the globe: fit for purpose?
Greg Koski, Alliance for Clinical Research Excellence and Safety (ACRES), Massachusetts General Hospital, Harvard Medical School, USA

15:00 Questions & Discussion

15:30 Summary & Conclusions from the Conference: Using the CTR to make us better.

15:40 End of the Conference